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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/883,848	06/18/2001	Leona E. Ling	CIBT-P01-119	9957
28120	7590	03/30/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			FETTEROLF, BRANDON J	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/883,848		LING ET AL.	
	Examiner		Art Unit	
	Brandon J. Fetterolf, PhD		1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,25-27 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 6 is/are allowed.
- 6) ☒ Claim(s) 1,2,25-27 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Ling et al.

Response to the Amendment

The Amendment filed on 12/27/2005 in response to the previous Non-Final Office Action (08/29/2005) is acknowledged and has been entered.

Claims 1-2, 25-27 and 35-42 are currently pending and under consideration.

Information Disclosure Statement

The Information Disclosure Statement filed on 1/3/2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

All rejections and/or objections are withdrawn in view of applicant's amendments and arguments there to.

New Rejections necessitated upon reconsideration:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 25-26, 35-36 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of a genus of hedgehog agonists which promote angiogenesis. As such, the claims encompass a genus of hedgehog agonist defined solely by its principal biological property, which is simply a wish to know the identity of any material with that biological property.

However, the written description in this case only sets forth a hedgehog polypeptide agonist consisting of the amino acid sequence of SEQ ID NOs: 10-18 or 23-26 and a small organic hedgehog agonist compound consisting of the general formula XII-XIX.

The Written Description Guidelines for examination of patent applications indicates, "the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical characteristics and/or other chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicant was in possession of the claimed genus." (Federal register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 column 3) and (see MPEP 2164).

The specification teaches (page 4, line 22 to page 5, line 16) that hedgehog agonists of the invention include, but are not limited to, agonists, which modulates hedgehog biological activity (i.e., elicits, allows and/or enhances hedgehog biological activity) such as polypeptides or small organic molecules. With regards to the polypeptides, the specification teaches (page 58, line 24 to page 58, line 4) the agonist is a hedgehog polypeptide with one or more of the following characteristics: (1) it has at least 30, 40, 42, 50, 60, 70, 80, 90 or 95 % sequence identity with a hedgehog sequence such as SEQ ID NOS: 10-18 or 23-26; (2) it has a cysteine or a functional equivalent as the N-terminal end; (3) it may induce alkaline phosphatase activity in C3H10T1/2 cells; (4) it has an overall sequence identity of at least 50%, preferably at least 60%, more preferably at least 70, 80, 90 or 95% with a polypeptide of a hedgehog sequence; (5) it can be isolated from natural sources such as mammalian cells; (6) it can bind or interact with patched; and (7) it may be hydrophobically-modified (i.e., it has at least one hydrophobic moiety attached to the polypeptide. With regards to the small molecule agonists, the specification teaches (beginning on page 70, line 32) that a small organic molecule may agonize hedgehog signal transduction via an interaction with but not limited to hedgehog, patched

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(ptc), gli, and/or smoothened. The specification further provides a number of small organic agonists contemplated for use as hedgehog agonist (beginning on page 71). Thus, while the specification contemplates any and/or all hedgehog agonist, the written description only reasonably conveys a hedgehog polypeptide agonist consisting of the amino acid sequence of SEQ ID NOs: 10-18 or 23-26 and a small organic hedgehog agonist compound consisting of the general formula XII-XIX. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to the genus that “constitute a substantial portion of the genus.” See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by “show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ...i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.” *Id.* At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., ___F.3d___, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of agonists that encompass the genus of hedgehog agonist, which promote angiogenesis. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

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Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of agonist, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only a hedgehog polypeptide agonist consisting of the amino acid sequence of SEQ ID NOs: 10-18 or 23-26 and a small organic hedgehog agonist compound consisting of the general formula XII-XIX, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Baron et al. (WO 98/35020, 1998).

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Baron et al. teach (page 5, lines 1-5 and page 53, lines 20-30) a method of treating a subject suffering from an ischemia in tissues containing mesodermally derived cells comprising administering a compound to the ischemic site so as to stimulate vascular growth, wherein the ischemia is myocardial ischemia and the compound is an agonist of a hedgehog-protein-receptor. With regards to the compounds, the WO document teach that compounds of the invention include, but are not limited to, molecules which interact with membrane proteins which initiate signal transduction pathways such as smoothened, patched and gli which regulate hematopoiesis and vascular growth; and include, but are not limited to, hedgehog proteins and synthetic agonists (page 17, line 26 to page 18, line 7). Thus, while Baron et al. does not explicitly teach that the administration of the agonist would promote angiogenesis, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure because the specification discusses (page 2, lines 10-16) that "Angiogenesis, the process of sprouting new blood vessels from existing vasculature and arteriogenesis, the remodeling of small vessels into larger conduit vessels are both physiologically important aspects of vascular growth in adult tissues". See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 25-27, 35-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (US 6,613,798, 2003) as evidenced by Pettet et al. (Proc. R. Soc. Lond. B 1996; 263: 1487-1493) in view of Ferrari et al. (Basic Res. Cardiol. 1995; 90: 52-54).

Porter et al teach small organic agonist that are capable of promoting proliferation in cells by modulating the hedgehog pathway, wherein the small organic agonists encompasses the claimed

small organic compounds of formula XII (column 6, formula I and column 19, lines 3-10). With regards to the hedgehog pathway, the patent teaches that the small organic agonist can modulate the signal transduction pathway regulated by hedgehog, patched (ptc), gli and/or smoothened (column 18, lines 40-43). Moreover, Porter et al. teach (column 54, lines 19-25) that the small organic agonist may be administered to a patient suffering from severe congestive heart failure (CHF) characterized by cardiac cachexia, as well as for promoting wound healing resulting from surgery, wherein the wound heals with less scarring (column 61, lines 8-27). With regards to the administration, the patent teaches that the agonist may be administered systemically (column 67, lines 1-8). Thus, while Porter et al. does not teach that wound healing is the promotion of angiogenesis, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure because as evidenced by Pettet et al., angiogenesis, the formation of blood vessels, is described as a process whereby capillary sprouts are formed in response to externally supplied chemical stimuli and occurs during wound healing (abstract). See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Porter et al. do not explicitly teach a method of improving myocardial function following myocardial ischemia, wherein the agonist promotes angiogenesis.

Ferrari comments on the clinical relevance of chronic left ventricular dysfunction, also referred to as “hibernating myocardium” (abstract). Specifically, the reference teaches that this condition may be present over months or years, or indefinitely in subjects with fibrosis, scar formation and remodeling after myocardial infarction, wherein the therapeutic implication with regards to regional and global left ventricular function due to hibernation will improve after revascularization and it is associated with improved survival (page 52, 1st column, 2nd to 3rd paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to administer to a patient a small organic hedgehog agonist as taught by Porter et al. following myocardial ischemia in view of Ferrari. One would have been motivated to do so because as evidenced by Ferrari, hibernating myocardium is identified by scar formation following myocardial infarction and can be improved after revascularization, e.g., angiogenesis. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by administering to a

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patient a small organic hedgehog agonist as taught by Porter et al. following myocardial ischemia in view of Ferrari, one would achieve a method of improving the survival of a patient following myocardial infarction.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter et al. (US 6,613,798, 2003) as evidenced by Pettet et al. (Proc. R. Soc. Lond. B 1996; 263: 1487-1493) and Ferrari et al. (Basic Res. Cardiol. 1995; 90: 52-54) in further view of Igo et al. (US 5,681,278, 1997)

Porter et al. and Ferrari teach, as applied to claims 1-2, 25-27, 35-38 and 42, a method of improving myocardial function following myocardial ischemia, comprising administering an amount of a small organic agonist effective to promote angiogenesis. With regards to the administration, Porter et al. and Ferrari teach that the agonist may be administered systemically (Porter et al., column 67, lines 1-8).

Porter et al. and Ferrari et al. do not explicitly teach that the agonist is administered by direct injection to ischemic myocardium, intrapericardial administration or by intracoronary catheter delivery.

Igo et al. teach method for treating blood vessels in a mammal, especially the coronary blood vessels (abstract). Specifically, the patent teaches that the blood vessels can be treated by administering an agent intracoronarily to reopen the thrombosed vessel and reduce the incidence of myocardial infarction or intrapericardial injection (column 3, lines 9-16 and column 6, lines 21-22). With regards to intrapericardial injection, Igo et al. teach that many agents have been injected into the pericardial space allowing for a site specific delivery of the agent which attains higher, longer lasting drug levels in the pericardial fluid with lower plasma concentrations and less systemic toxicity (column 6, lines 23-28).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the routes of administration of the small organic hedgehog agonist as taught by Porter et al. for the treatment of a patient following myocardial infarction. One would have been motivated to do so because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Moreover, as taught by Igo et al., intrapericardial administration allows for a site specific

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delivery of the agent which attains higher, longer lasting drug levels in the pericardial fluid with lower plasma concentrations and less systemic toxicity. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by optimizing the administration routes of the small organic hedgehog agonist as taught by Porter et al., one would achieve a method of selectively targeting the blood vessels of a patient following myocardial infarction.

Claims 26-27, 35-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baron et al. (WO 98/35020, 1998) in view of Porter et al. (US 6,613,798, 2003) as evidenced by Pettet et al. (Proc. R. Soc. Lond. B 1996; 263: 1487-1493).

Baron et al. teach, as applied to claims 1-2 and 25 above, a method of treating a subject suffering from an ischemia in tissues containing mesodermally derived cells comprising administering a compound to the ischemic site so as to stimulate vascular growth, wherein the ischemia is myocardial ischemia and the compound is an agonist of a hedgehog-protein-receptor (page 5, lines 1-5 and page 53, lines 20-30). With regards to the compounds, the WO document teaches that compounds of the invention include, but are not limited to, molecules which interact with membrane proteins which initiate signal transduction pathways such as smoothened, patched and gli which regulate hematopoiesis and vascular growth; and include, but are not limited to, hedgehog proteins and synthetic agonists (page 17, line 26 to page 18, line 7).

Baron et al. do not explicitly teach that the synthetic agonist is a hedgehog agonist having a molecular weight of less than 25000 amu, such as the compounds disclosed in claim 27. Nor does Baron et al. teach that the compound is administered systemically.

Porter et al. teach small organic agonist that are capable of promoting proliferation in cells by modulating the hedgehog pathway, wherein the small organic agonists encompasses the claimed small organic compounds of formula XII (column 6, formula I and column 19, lines 3-10). With regards to the hedgehog pathway, the patent teaches that the small organic agonist can modulate the signal transduction pathway regulated by hedgehog, patched (ptc), gli and/or smoothened (column 18, lines 40-43). Moreover, Porter et al. teach (column 54, lines 19-25) that the small organic agonist may be administered to a patient suffering from severe congestive heart failure (CHF) characterized by cardiac cachexia, as well as for promoting wound healing resulting from surgery, wherein the wound heals with less scarring (column 61, lines 8-27). With regards to the

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administration, the patent teaches that the agonist may be administered systemically (column 67, lines 1-8). Thus, while Porter et al. does not teach that the administration of the agonist would promote angiogenesis, the claimed functional limitation is an inherent property of the referenced method because as evidenced by Pettet et al., "Angiogenesis, the formation of blood vessels, may be described as a process whereby capillary sprouts are formed in response to externally supplied chemical stimuli.... occurs during wound healing..." (abstract). Thus, it does not appear that the claim language or limitation results in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to substitute the a small organic hedgehog agonist as taught by Porter et al. for the hedgehog protein used in the method of treating a subject suffering from myocardial ischemia as taught by Baron et al.. One would have been motivated to do so because each have been individually taught in the prior art to be effective at stimulating vascular growth, i.e. wound healing and/or angiogenesis. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by administering small organic hedgehog agonist as taught by Porter et al., one would achieve a method of promoting wound healing, e.g. angiogenesis, in a patient following myocardial infarction.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baron et al. (WO 98/35020, 1998) in view of Igo et al. (US 5,681,278, 1997).

Baron et al. teach, as applied to claims 1-2 and 25 above, a method of treating a subject suffering from an ischemia in tissues containing mesodermally derived cells comprising administering a compound to the ischemic site so as to stimulate vascular growth, wherein the ischemia is myocardial ischemia and the compound is an agonist of a hedgehog-protein-receptor (page 5, lines 1-5 and page 53, lines 20-30). With regards to the compounds, the WO document teaches that compounds of the invention include, but are not limited to, molecules which interact with membrane proteins which initiate signal transduction pathways such as smoothened, patched and gli which regulate hematopoiesis and vascular growth; and include, but are not limited to, hedgehog proteins and synthetic agonists (page 17, line 26 to page 18, line 7).

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Baron et al. do not explicitly teach that the agonist is administered by direct injection to ischemic myocardium, intrapericardial administration or by intracoronary catheter delivery.

Igo et al. teach method for treating blood vessels in a mammal, especially the coronary blood vessels (abstract). Specifically, the patent teaches that the blood vessels can be treated by administering an agent intracoronarily to reopen the thrombosed vessel and reduce the incidence of myocardial infarction or intrapericardial injection (column 3, lines 9-16 and column 6, lines 21-22). With regards to intrapericardial injection, Igo et al. teach that many agents have been injected into the pericardial space allowing for a site specific delivery of the agent which attains higher, longer lasting drug levels in the pericardial fluid with lower plasma concentrations and less systemic toxicity (column 6, lines 23-28).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the routes of administration of the hedgehog agonist as taught by Baron et al for the treatment of a patient following myocardial infarction. One would have been motivated to do so because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A. Moreover, as taught by Igo et al., intrapericardial administration allows for a site specific delivery of the agent which attains higher, longer lasting drug levels in the pericardial fluid with lower plasma concentrations and less systemic toxicity. Thus, one of ordinary skill in the art would have a reasonable expectation of success that by optimizing the administration routes of the hedgehog agonist as taught by Baron et al., one would achieve a method of selectively targeting the blood vessels of a patient following myocardial infarction.

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
3/17/06